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EVALUATION OF SIX CHEST DRAINAGE UNITS FOR USE IN AEROMEDICAL EVACUATION

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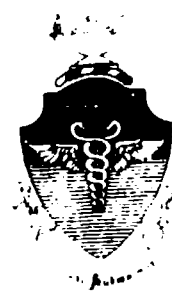
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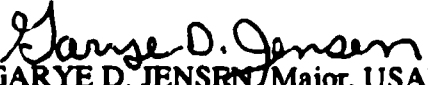
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The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

This report has been reviewed and is approved for publication.


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EVALUATION OF SIX CHEST DRAINAGE UNITS FOR USE IN AEROMEDICAL EVACUATION

BACKGROUND

The Aeromedical Research Function of the USAF School of Aerospace Medicine (USAFSAM) has completed observational performance testing on six different brands of Chest Drainage Units (CDU). The testing program was designed to observe and measure each unit's characteristics in a simulated operational aeromedical evacuation environment. The information presented describes the operational response of the Chest Drainage Units to the stresses of flight and the special operating instructions which apply to some of the units.

The Chest Drainage Units tested include:

- Argyle Sentinel Seal Dual Chest Drainage Unit
- Migada Underwater Chest Drainage Unit
- Pleur-Evac Adult-Pediatric, Model A-4000
- Pleura Gard Chest Drainage System
- Thora Drain III Underwater Drainage System
- Thora-Klex Chest Drainage Unit

The Pleur-Evac was previously evaluated and recommended for use in aeromedical evacuation by this office based on data gathered during hypobaric chamber experiments using an animal model. It was included in this test to obtain a complete database of the operational characteristics of chest drainage units used in aeromedical evacuation.

The Pleura Gard, Thora Drain, and Thora-Klex were evaluated at the request of Military Airlift Command/SGNL. The Argyle and Migada were evaluated at the request of the manufacturers. They were received after the start of the evaluation. Because the in-flight feasibility test was performed first, these units did not complete this test.

In-flight feasibility is typically performed last after all possible safety concerns have been addressed. The units have no electrical parts; therefore, electromagnetic interference (EMI) was not a problem. The units have no trapped gases; therefore, there were no hazards associated with changing barometric pressure or rapid decompressions. By performing the in-flight feasibility test first, we were able to observe which operational characteristics would present the greatest challenge to the aeromedical crewmembers. The laboratory tests were then designed to measure how

the individual stresses of flight and the use of a Heimlich valve and/or applied suction affected the operation of the chest drainage unit.

A CDU is used to remove air and liquid from a patient's pleural cavity. Most units are divided into three separate chambers. These units operate like the 3-bottle underwater seal chest drainage system (Fig 1).

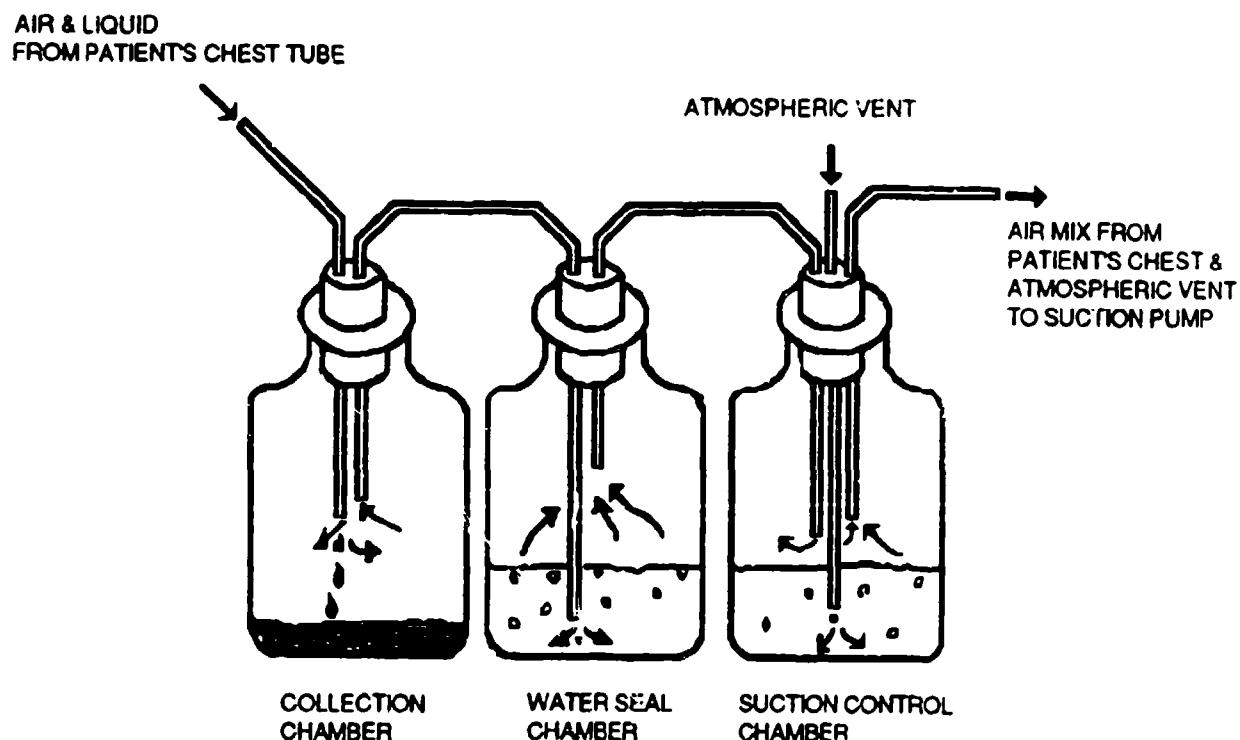


Figure 1. Normal operation of the 3-bottle underwater seal chest drainage system.

A chest tube allows air and liquid to drain from the patient's pleural cavity into the collection chamber. Liquid accumulates and is measured in the collection chamber; air flows out of this chamber and into the water seal chamber by bubbling

out of the tube below the water seal. The air now travels out of the water seal chamber and into the suction control chamber.

CDUs which will only operate in the gravity drain configuration do not need a suction control chamber. The air leaving the water seal chamber can vent directly to the atmosphere. If the suction control chamber is permanently attached to the drainage unit, the air will still vent to the atmosphere if the suction control chamber is not filled with water.

CDUs which operate with applied suction, usually regulate the amount of suction applied to the pleural cavity by varying the water level in the suction control chamber. As the chamber's water level is increased, more air is pulled into the pump through the collection chamber. As the water level is decreased, more air is drawn from the atmospheric vent through the suction control chamber and into the pump.

Appendixes A, B, and C describe the air and water flow patterns of the 3-bottle chest drainage system during normal operation, operation during cabin ascent, and operation during cabin descent.

METHODS

We developed test procedures to evaluate the safety and human factors issues associated with the operation of the CDUs tested. The overriding question was "how do the CDUs operate in flight compared to their operating characteristics on the ground?" An initial inspection was performed to determine each CDU's operational characteristics on the ground in four different configurations. These baseline observations were compared with the observations made during subsequent tests. The operational characteristic of primary interest was the negative pressure measured at the patient end of the chest drainage system as a function of the CDU's configuration and the individual stresses of flight. The individual stresses considered were vibration, hot and cold storage, altitude, and rapid decompression.

Each chest drainage unit is capable of operating in four different configurations:

1. With Heimlich Valve and With Applied Suction
2. With Heimlich Valve and With Gravity Drain
3. Without Heimlich Valve and With Applied Suction
4. Without Heimlich Valve and With Gravity Drain

The units were tested in each configuration during the altitude and rapid decompression experiments. During the vibration and environmental experiments,

the units were only tested with the Heimlich valve and applied suction (configuration #1). Only one configuration was tested because these units are only expected to operate for one 24-h period and the vibration and environmental tests are both very long compared to the unit's life expectancy. The Heimlich valve and applied suction configuration was used during these tests because a CDU is only used in aeromedical evacuation with a Heimlich valve and measured pressure variations are more apparent with applied suction than in the gravity drain configuration.

During the applied suction configuration, the Impact 308M Portable Aspirator was used as the continuous suction source. The suction, negative pressure, delivered to the CDU fluctuated only slightly during operation, averaging 60 cm H₂O. It was not possible to obtain lower negative pressures than this from the Impact suction unit.

In the first two configurations tested, the tube, which ran from the unit's collection chamber, was attached to the exhaust end of the Heimlich valve. The patient's side of the valve was connected to a pressure transducer which measured the pressure applied to the transducer relative to the barometric pressure surrounding the transducer. In the second two configurations, the tube from the collection chamber was attached directly to the pressure transducer. The pressure transducer continuously measured the pressure at the patient's side of the chest drainage system. The pressures were recorded, once every 15 s, on a Grant 1200 series Squirrel Meter/Logger data recorder. The recorded pressures were used to compare different chest drainage units operating under similar configurations to each other and to compare the different configurations of the same unit.

The measured pressures cannot be used to determine the pressure of a chest drainage configuration on an actual patient. The pressure transducer does not directly model all of the variations in the pleural cavity (such as bleeding and air leaks); a patient will introduce air and liquid into the chest drainage unit - a pressure transducer will not. The actual pressure inside a patient's pleural cavity depends in part on the amount of air and fluid expelled into the pleural cavity and varies with each breath cycle. The measured pressures though are a good method of determining how the pressure in the chest will be affected by a CDU during changing environmental conditions.

Initial Inspection

During the initial inspection, each CDU was tested in each of the four configurations for visible cracks or defects, water and/or air leaks, and the ability to deliver the desired pressure to the pressure transducer ("measured pressure"). In the applied suction configuration, the desired pressure was 20 cm H₂O negative pressure; in the gravity drain configuration, the desired pressure was zero.

Electromagnetic Interference

This test was not performed because CDUs do not have any electrical components.

In-flight Feasibility

In-flight feasibility testing was performed to observe the operational characteristics of the units under aeromedical evacuation conditions. Results of this test determined which laboratory tests were necessary to evaluate the CDU's operational response and identify special operating instructions.

Vibration

While operating, each unit was vibrated in its X, Y, and Z axes separately. During the sinusoidal test, the vibration frequency was cycled smoothly from 5 Hz to 500 Hz and back to 5 Hz five times. This test took 1 h and 15 min for each of the 3 axes. During the random test, the vibration frequency was varied between 5 Hz and 500 Hz randomly for 30 min for each of the 3 axes.

During the test, each unit was hung from a litter test stand and set up in the operational mode according to current operational practices. The litter test stand was attached to the vibration table. The pressure transducers, Heimlich valves, and suction pumps were set up on nonvibrating surfaces so that the measured pressures would only be affected by changes from the vibrating chest drainage units.

Environmental

Hot and cold storage tests were performed. The hot storage temperature was 140 °F (60 °C); the cold storage was -40 °F (-40 °C). Prior to each test, the units were cleaned and dried. After 6 h at the storage temperature, the environmental chamber was returned to approximately 78 °F (26 °C), and the units were allowed to equilibrate. As each unit was removed from the chamber, it was visually inspected for defects, filled, and operated with the Heimlich valve and applied suction. Following 20 min of operation, the units were inspected for air and water leaks, and the measured pressure was recorded.

Altitude

Altitude tests were performed in the USAFSAM hypobaric chambers. Altitudes above ground level are simulated by decreasing the barometric pressure

within the chamber to that corresponding to the desired altitude. Therefore, without ever "leaving the ground," the effects of changing altitude can be observed and measured in the chamber. During these tests, the equipment was directly monitored and operated by the investigator.

Each unit was tested at least once in each of the four configurations. Each test started with approximately 2 min of ground operation to record the initial set-point (desired) pressure. The chamber then ascended to an equivalent pressure altitude of 10,000 ft at a rate of 500 ft/min by decreasing the barometric pressure from 760 mm Hg to 523 mm Hg. After 20 min at 10,000 ft, the chamber descended back to ground level at 500 ft/min. The test was concluded after approximately 5 min of ground operation.

Rapid Decompression

Rapid decompression tests were performed in the USAFSAM hypobaric chambers using the same principle of reducing the barometric pressure within the chamber to that corresponding to the desired altitude. During this test, only the CDUs, suction pumps, and pressure sensors were in the chamber. The data recorder and investigator remained outside of the chamber. The test was observed through the chamber windows.

Most of the units were tested at least once in each of the four configurations. Each test started with approximately 2 min of ground operation. The chamber then ascended to an equivalent pressure altitude of 8,000 ft at a rate of 500 ft/min. After the units stabilized (3 to 5 min) at 8,000 ft, the chamber was rapidly decompressed to an equivalent altitude of 40,000 ft in 1 s. Chamber pressure remained at a 40,000-ft altitude equivalent until the units stabilized (3 to 5 min) and was increased to a ground level equivalent at a rate of 5,000 ft/min. The second and third rapid decompressions (RD) were performed over 7 to 60 s. (The actual RDs occurred in a random order.)

RESULTS

Initial Inspection

All of the CDUs except the Migada were able to deliver the desired pressure in all four configurations. The Migada does not have a suction control mechanism; therefore, the measured pressure during the applied suction tests (with or without the Heimlich valve) was equal to that supplied by the suction source. The Migada averaged 60 cm H₂O negative pressure while the desired pressure was 20 cm H₂O negative pressure.

The Impact suction pumps were adjusted to deliver the lowest suction pressure possible. The Impact's suction pressure could not be adjusted low enough to allow the "gentle bubbling" in the suction control chamber which is described in the operating instructions of most units. The "vigorous bubbling" observed in these units did not seem to adversely affect the measured pressure.

In-flight Feasibility

The in-flight feasibility tests were performed on the C-9A aeromedical evacuation aircraft. During the tests, the measured pressure was recorded while the units were operated in the applied suction with Heimlich valve configuration #1. The Thora-Klex, Thora Drain, and Pleura Gard Units were tested. Results indicate that both vibration and barometric pressure changes influence the unit's measured pressure. As a general observation, the measured pressure increased (became less negative) during ascent and decreased (became more negative) during descent. The measured pressures also appeared to be affected by the aircraft's vibration; the measured pressure would fluctuate slightly about an average value during flight and then stabilize after landing when the aircraft engines were turned off.

Additionally the changing barometric pressure affected the water levels within the suction control and water seal chambers during ascent and descent. During ascent, air from the collection chamber would bubble out of this chamber through the water seal into the water seal chamber; then the air would bubble out of the water seal chamber into the suction control chamber, and finally exhaust into the aircraft's environment. During descent, water from the suction control and water seal chamber appeared to be pushed into the collection chamber.

During the flight, it was necessary to closely monitor the water levels in the water seal and suction control chambers. As cabin air was drawn through the suction control chamber by the Impact suction pump, the water in this chamber would quickly evaporate. This water loss, combined with the redistribution of the water within these chambers during aircraft descents, made it necessary to frequently add water to the suction control chamber. It was also necessary to add water to the water seal chamber after aircraft descents.

During the cruise phase of flight, the thumb screw on the Thora-Klex was observed "walking" in and out of its housing, thereby changing the measured pressure; this was attributed to aircraft vibration.

Environmental

All the units successfully passed the environmental tests.

Vibration

Structurally, all the units passed the vibration tests. They remained attached to the test litter and did not develop air or water leaks.

The Thora-Klex uses a "thumb screw" adjustment for suction control. As observed in flight, at certain frequencies of vibration, the thumb screw would "walk" in and out of its housing. This would cause variations in the measured pressure of 8.8 to 41.4 cm H₂O negative pressure.

The Argyle's suction control regulator unthreaded itself once during the Z-axis test (vertical vibration); it was immediately replaced without interrupting the rest of the test.

Altitude

Several altitude tests were necessary to determine what was happening inside each of the chest drainage units. Figure 2 shows the general response of all of the CDUs in each configuration to the changing barometric pressure occurring during normal aeromedical evacuation flights. Basically, from the set-point pressure, the measured pressure would increase slightly during ascent from ground level to the 10,000-ft equivalent pressure altitude. If the set-point pressure was zero (gravity drain configurations), the measured pressure at ground level was zero; during ascent the measured pressure would increase to approximately 2 to 3 cm H₂O positive pressure. During the applied suction configurations, the set-point pressure was approximately 20 cm H₂O negative pressure; during ascent, the measured pressure increased to approximately 17 cm H₂O negative pressure. For all configurations, the measured pressure would return to the set-point pressure when the chamber's altitude stabilized at 10,000 ft.

During descent, the measured pressure for all units in any configuration would decrease - become more negative. For most units, the measured pressure would vary between 24.5 and 65.0 cm H₂O negative pressure regardless of operating configuration. In the applied suction configurations, the Migada's measured pressure varied from 73.8 to 102.2 cm H₂O negative pressure. The Argyle varied from 160.4 to 216.6 cm H₂O negative pressure.

The large negative pressure delivered by the Migada stems from its lack of a suction control mechanism. Although the desired negative pressure was 20 cm H₂O, the set point pressure (starting pressure at ground level) was approximately 60 cm H₂O negative pressure. The Migada's measured pressure decrease from 60 to

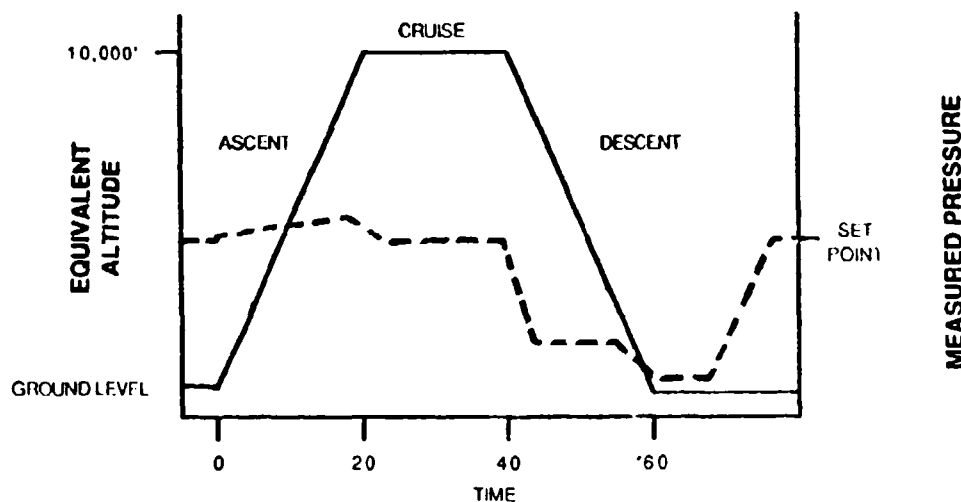


Figure 2. Flight profile and typical CDU reaction during the altitude test.

— Altitude Profile
 --- Measured Pressure

102 cm H₂O negative pressure is comparable to another unit's measured pressure decrease of 20 to 70 cm H₂O negative pressure.

The Argyle has a "stopper" incorporated in the water seal chamber and the patient assessment (suction control) chamber. These stoppers prevent cabin air from entering the unit through the atmospheric vent. The introduction of cabin air into the CDU equalizes the pressure between the unit and the cabin atmosphere and reduces the measured negative pressure. The tradeoff is that while the Argyle effectively prevents cabin air from entering the CDU's collection chamber, doing so generates a large negative measured pressure. The negative pressure may be reduced by opening the manual vent. This action allows cabin air to enter the unit and equalize the pressures within the different chambers.

Whenever cabin air is introduced into any unit, it bubbles through the suction control chamber into the water seal chamber and finally into the collection chamber. During this process, the air often carries water from the suction control chamber into the water seal chamber and then into the collection chamber. At the end of this process, the water levels in the suction control and water seal chambers have been reduced and the fluid volume in the collection chamber has been increased.

For all of the units tested, the addition of the Heimlich valve did not have a significant effect on the measured pressure.

Rapid Decompression

During the rapid decompression experiments, the measured pressure of all of the units, regardless of configuration, was positive. The measured pressure increase occurred as the chamber's barometric pressure was reduced from an equivalent pressure altitude of 8,000 ft to 40,000 ft. It was caused as the air inside the CDU expanded and forced its way out of the unit. Frequently during the 1s and 7 s RDs, the air would move through the water seal chamber so fast that it would drag the water along with it. This action would leave the CDU with low water levels in the water seal and suction control chambers after the RD. The measured pressures returned to their approximate set point after approximately 5 min at 40,000 ft.

During descent, the measured pressures ranged from 0.8 to 262.6 cm H₂O negative pressure. Results indicate that the measured pressure does not depend on the type of CDU tested, the CDU's configuration, or the length of the RD; in fact, no particular pattern was evident.

The Migada was only tested with the Heimlich valve because during descent water from the collection chamber (which doubles as the water seal) was first forced up into the collection tube; then bubbles of air and water were forced into the tube--sometimes as far as the Heimlich valve. The Migada was not tested without the Heimlich valve to protect the pressure sensor from possible water damage.

CONCLUSIONS

Experimental results were reviewed by Dr Leach, Chief of Thoracic Surgery, Wilford Hall USAF Medical Center, Lackland AFB, TX. Basically, although there is a wide range of measured pressures, there is no clinical evidence suggesting that any of the units used in aeromedical evacuation would be harmful to a patient. Therefore, all of the units are recommended for approval for aeromedical evacuation use; but there are important points that should be considered during their use.

For patient safety, a Heimlich valve should be used with every type of chest drainage unit. The addition of a Heimlich valve does not adversely affect the

operation of the CDU or the measured pressure, and it should be placed as close as possible to the patient's chest tube.

Monitor the water levels in the water seal and suction control chambers closely; add water as necessary prior to takeoff and after stabilization at the cruising cabin altitude. Dry cabin air will cause the water to evaporate quickly, especially the water in the suction control chamber. Generally, it is not necessary to adjust the water levels during ascent or descent.

On the ground, after every descent, slowly vent or open the unit to equalize the pressure between the collection chamber and the atmosphere. The Heimlich valve will prevent air from entering the patient's pleural cavity. After the pressure has equalized, readjust the water levels in the water seal and suction control chambers as necessary. This is a very important step for any unit which is separated into 3 chambers; during descent the water seal may have been forced into the collection chamber and the patient is protected only by the Heimlich valve. To restore the CDU to working order, the water levels in the water seal and suction control chamber must be reestablished!

Multiple descents may increase the liquid level in the collection chamber to the point that it would be necessary to change or drain the collection chamber more frequently than during ground operation.

At the end of a day's flight or at least once every 24 h, remove and replace the Heimlich valve and chest drainage unit under sterile conditions.

All units experienced a slight increase in the measured pressure during ascent. This increase averaged 2 to 3 cm H₂O positive pressure above the initial set-point pressure. While this is barely noticeable in the applied suction configuration, it can cause a slight positive pressure to develop in the patient's collection tube when the gravity drain configuration is used. Patients who require a definite negative pressure should be connected to a CDU in the applied suction configuration.

The Argyle most effectively prevents air from entering the collection chamber during descent; but this unit had the greatest negative measured pressure. It is possible to manually vent this unit to reduce the negative pressure in the system to the desired level.

The Migada and Thora-Klex units do not have the ability to provide accurate, controllable suction to the patient. If controllable suction is required, one of the other units should be used.

In the event of a rapid decompression, nothing can be done to prevent the positive pressure that occurs as the air inside the unit moves into the cabin's atmosphere. It is possible that the water seals will be blown out of the unit with the air, but the Heimlich valve will continue to separate the patient from the cabin's atmosphere. As soon as possible, reestablish the water levels and continue to operate the unit as normal.

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APPENDIX A

FUNDAMENTALS OF UNDERWATER SEAL CHEST DRAINAGE Normal Operation

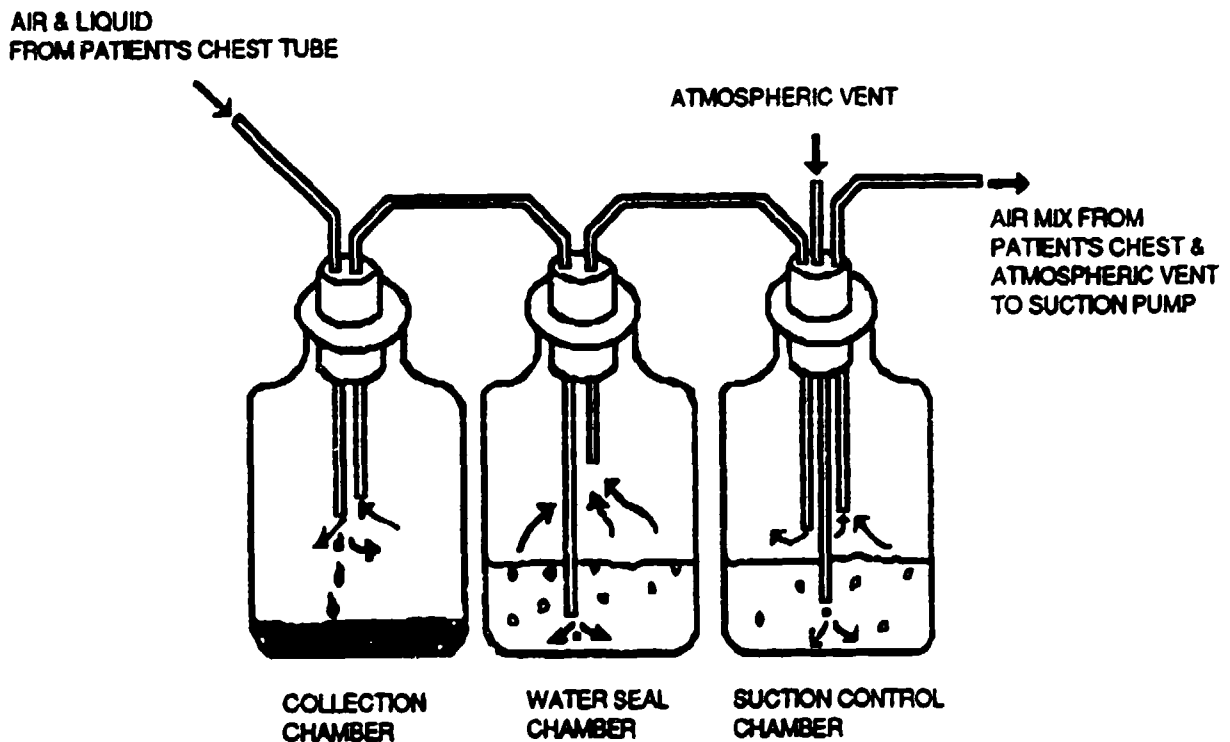


Figure A-1
Normal Operation

Air and liquid from the patient's pleural cavity move from a region of high pressure to a region of lower pressure. Liquid remains at the bottom of the Collection Chamber while air is forced out through the connecting tube, released under the water seal, and bubbles into the Water Seal Chamber. The air is forced out through the second connecting tube into the Suction Control Chamber. Here the air from the pleural cavity mixes with cabin air which bubbles through the suction control water level from the atmospheric vent. The air mixture is forced out through the last tube into the suction pump. In the gravity drain configuration, the Suction Control Chamber is not filled with water, air forced from the Water Seal Chamber exhausts into the atmosphere through the atmospheric vent and suction pump connection tube.

APPENDIX B

FUNDAMENTALS OF UNDERWATER SEAL CHEST DRAINAGE Ascent

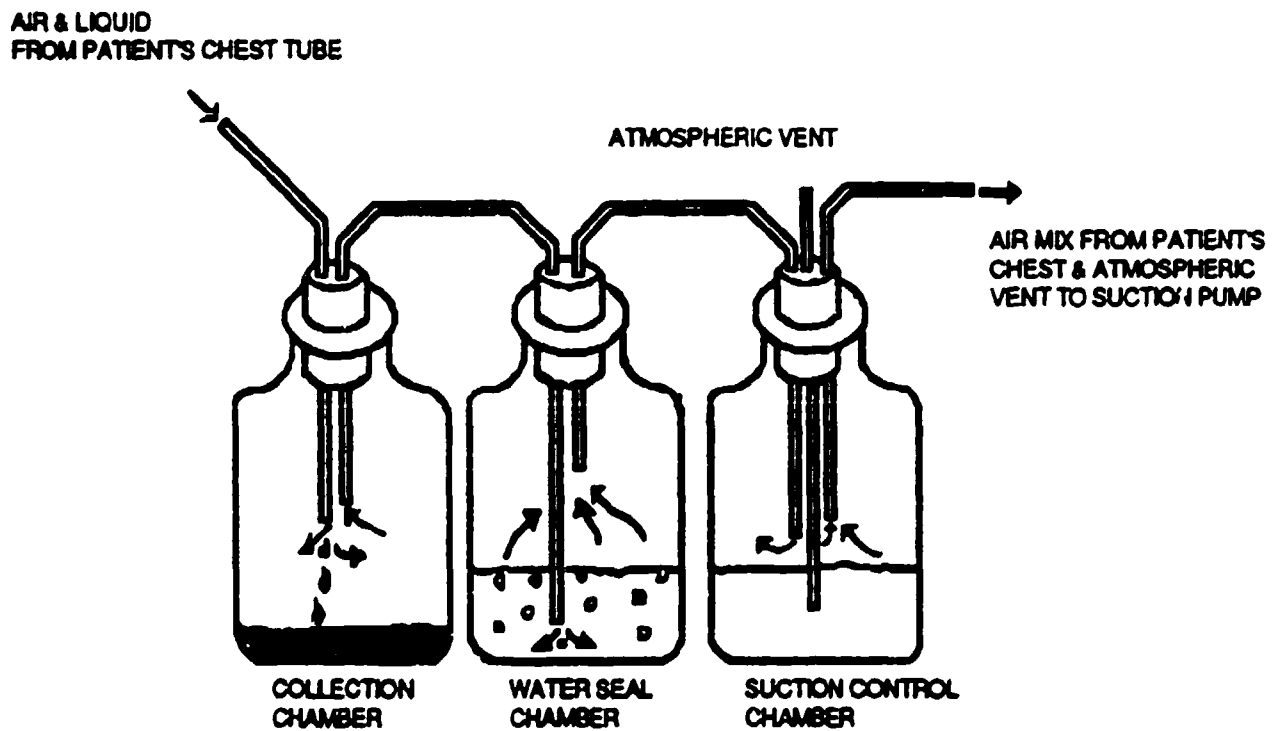


Figure B-1
Ascent

Air and liquid from the patient's pleural cavity continue to drain into the Collection Chamber. During ascent, air in the chambers expands causing a slight increase in the measured pressure. The expanding air in the Collection Chamber is forced through the connecting tube and bubbles out from the water seal into the Water Seal Chamber. The air is then forced out through the second connecting tube into the Suction Control Chamber. From there, it is forced out of the unit into the suction pump. The air in the chest drainage unit is expanding in response to the decreasing cabin pressure. Little or no cabin air enter the unit through the atmospheric vent during descent. At the cruising altitude, the pressure within the unit equalizes and the drainage system operates as it did on the ground.

APPENDIX C

FUNDAMENTALS OF UNDERWATER SEAL CHEST DRAINAGE

Descent

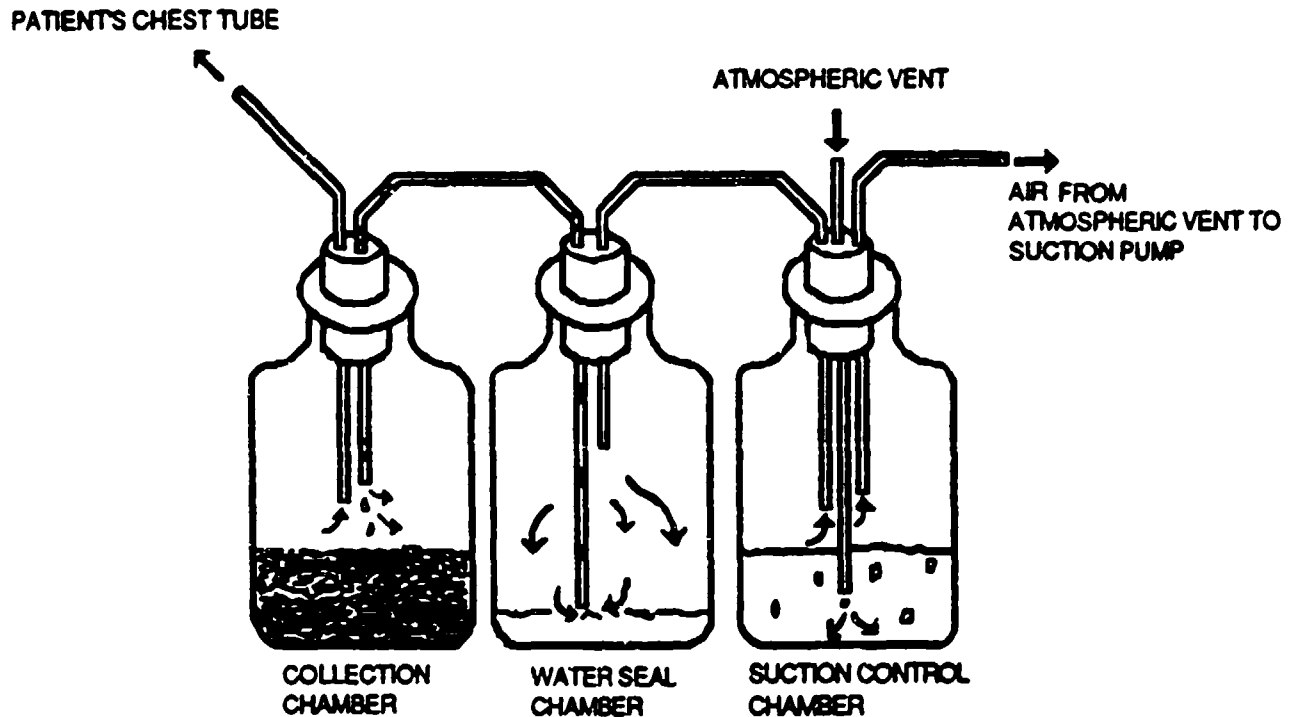


Figure C-1
Descent

During descent, air inside the unit contracts causing a decrease in the measured pressure. To equalize the pressure, cabin air enters the unit through the atmospheric vent and bubbles through the suction control water level. From the Suction Control Chamber some air is drawn into the suction pump. Air is also forced backwards through the connecting tube into the Water Seal Chamber. As the air pressure increases above the water seal, it forces the water up the connecting tube and into the Collection Chamber. Soon the water level is reduced so that it is equal with the tube's opening. Now water and air bubble into the Collection Chamber. After enough cabin air either works its way into, or is manually vented into the Collection Chamber, the pressure equalizes and the unit begins to operate like it did prior to ascent. The only difference is that the water seal level may be reduced and is not effective.